K0 33767

FEB 2 4 2004

EXHIBIT 2

Jeil Medical Corporation
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Kuro-Ku,
Seoul, KOREA
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Revised February 17, 2004
Contact: N.K.Kim, R&D Director

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: Dual Top Anchor System Screws (various models)
   Classification Name: Implant, Endosseous, Product Code DZE
   Common/Usual Name: Bone Screw

2. Equivalent legally marketed devices: OsteoMed Orthodontic Screw System, (K031936), Straumann Ortho Implant (K982509) the Nobel Biocare Inplant Orthodontic Anchor System (K000643)..

3. Indications for Use (intended use) . This device is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only. For use in adults over the age of 12.

4. Description of the Device: This device is designed for orthodontic use. The screws are made of titanium alloy (ASTM F 136-98). The head of the screw is dual head type. The upper head is a hex type. There is a hole in the screw head through which a wire can be passed to fix the mandible and maxilla in orthodontic treatment. Also, Dual head design of screw accommodates the use of the screw with the orthodontic appliances (bracket, wire, and elastic band etc.) The tip of the screw is designed available to self-drilling and self-tapping. (Surgeon's option) This device is comprised of screws ranging in diameter of 1.4mm to 2.0mm and in length ranging from 6.0mm to 12mm. These screws are provided non-sterile. Therefore, this device must be sterilized prior to use. Steam sterilization is recommended. This device is provided with Polyethylene package. The top of packaging bag is sealed with sealing strip.

5. Potential Adverse Affects and Complications: (Common to all devices of this type)
   - Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device or premature loss of fixation with the bone, leading to nonunion.
   - Migration, bending, fracture or loosening of the implant.
   - Metal sensitivity, or allergic reaction to a foreign body.
   - Pain, discomfort, or abnormal sensation due to the presence of the device.
   - Increased fibrous tissue response around the fracture site and/or the implant.
   - Necrosis of bone.
   - Inadequate healing.

   Apart from these adverse effects there are always possible complications of any surgical

procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant

6. Safety and Effectiveness, comparisons to predicate devices:

Device Name	**Nobel Biocare Inplant Orthodontic Anchor System**	**OsteoMed Orthodontic Screw System,**	**Dual Top Anchor System Screws (various models)**
Device Classification Name	Implant, Endosseous, Product Code DZE	Implant, Endosseous, Product Code DZE	Implant, Endosseous, Product Code DZE
Applicant	Nobel BioCare	Osteomed	Jeil Medical Corporation
510(K) Number	(K000643).	(K031936)	(This submission)
Material	Titanium	Titanium Alloy	Titanium Alloy (ASTM F 136-98)
Intended use	This device is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only.	This device is used as an anchorage for orthodontic treatment in the mouth.	This device is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only. For use in adults over the age of 12.
Single Use?	YES	YES	YES
Supplied Sterile?	No comment	Non sterile, steam sterilize before use	Non sterile, steam sterilize before use

7. Conclusion: In all respects, the Dual Top Anchor System Screws (various models) Bone Screws are the equivalent of currently marked devices. They are made of the same materials and have similar dimensions and characteristics. Potential adverse effects are identical to those of predicate devices. This device is manufactured from material of titanium alloy (ASTM 136-98) that is used generally in this kind of bone screw. Similar devices made from titanium alloy (ASTM 136-98) to this device are manufactured and sold around the world. This device is substantially equivalent in design, material, intended use and function to the products on the table above. These devices are certified by notified body for CE.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 4 2004

Jeil Medical Corporation
C/O Mr. Daniel Kamm
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K033767
Trade/Device Name: Jeli Medical Corporation: Dual Top Anchor Systems Screws
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: November 20, 2003
Received: December 3, 2003

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

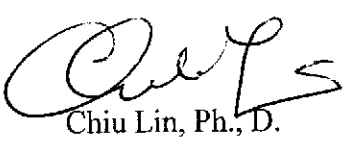
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033767

Indications for Use

510(k) Number (if known): K033767

Device Name: Jeil Medical Corporation: Dual Top Anchor System Screws

Indications For Use:

This device is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only. For use on adults over the age of 12.

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033767

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)